PAINLESS TATTOO 2- lidocaine cream Sambria Pharmaceuticals, LLC

Drug Facts

Active ingredient

Lidocaine 4%

Purpose

External Analgesic

Uses

For temporary relief of pain and itching.

Warnings

For external use only.

Do not use onwounds or damaged skin, in large quantities, or if you are allergic to any ingredients of this product.

When using this productuse only as directed. Avoid contact with the eyes, rashes, or mucous membranes.

Stop use and ask doctor ifcondition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

Keep out of reach of children and petsIf swallowed get medical help or contact a Poison Control Center right away.

Directions

Adults and children 12 years of age and over:

Clean and dry affected area, apply to affected area not more than 3 to 4 times daily.

Children 12 years of age or younger: ask a doctor.

Other Information

Protect this product from excessive heat and direct sun.

Inactive Ingredient

Agua (Deionized Water), Arnica Montana Flower Extract, C13-14 Isoparaffin, Chondroitin Sulfate, Emu Oil, Ethoxydiglycol, Ethylhexylglycerin, Glucosamine Sulfate, Isopropyl Palmitate, Laureth-7, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Methylsulfonylmethane (MSM), Phenoxyethanol, Polyacrylamide, Propylene Glycol, Stearic Acid, Triethanolamine

Product label





PAINLESS TATTOO 2 lidocaine cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54723-016	
Route of Administration	TOPICAL			
Active Ingredient/Active Meiety				
Active Ingredient/Active Moiety				

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	
EMU OIL (UNII: 344821WD61)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118X02B)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
LAURETH-7 (UNII: Z95S6G8201)	
TEA TREE OIL (UNII: VIF565UC2G)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYACRYLAMIDE (CROSSLINKED; 2 MOLE PERCENT BISACRYLAMIDE) (UNII: 9FPL31B58Q)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 903K93S3TK)	

Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54723-016- 01	4 mL in 1 PACKET; Type 0: Not a Combination Product	09/26/2023	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M017	09/26/2023		

Labeler - Sambria Pharmaceuticals, LLC (078676259)

Revised: 5/2024 Sambria Pharmaceuticals, LLC